Amendment #2
to RFP-NIH-NIAID-DMID-03-32

"Antibody Production Facility"

Amendment to Solicitation No.:	NIH-NIAID-DMID-03-32
Amendment No.:	2
Amendment Date:	October 24, 2002
RFP Issue Date:	September 20, 2002
Issued By:	Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Elizabeth Osinski, Contract Specialist
Name and Address of Offeror:	To All Offerors

The above numbered solicitation is amended as set forth below:

Below are questions and answers concerning this RFP.

Question 1 Reference: Sections L.2.a. (9-14) and M.2 (a.) – require the offeror to address a comprehensive suite of Human Subject Requirements. The Statement of Work, Note #1 states that the cost of the clinical trials should not be included in the cost proposal.

Since clinical trials will not be conducted under this resultant contract but only the products produced under this contract must be suitable for human clinical trials, the RFP is amended below to delete the sections which require the offeror to address human subject requirements.

Question 2 Will the government consider exempting resumes from the 200 page limit? The RFP requires that resumes include a listing of relevant publications, accomplishments, etc.

The Government will be increasing the page limitations for the technical proposal to 250 pages. Offerors may include relevant publications as attachments in an Appendix and the relevant publications are the only part of any appendixes that will be exempted from the 250 page limit.

Question 3 Please clarify what the Government will provide to the offeror as the "starting" material for task one.

The Government will most likely provide a cell line, although it could be DNA encoding the antibody. For purposes of the cost proposal, assume a cell line. See Amendment #1 to the RFP.

Question 4 Clarify whether the deliverables for Task Order #2 are only chimeric antibodies.

Deliverables may be chimeric and/or humanized antibodies; however, for purposes of the cost proposal assume the deliverable is a chimeric antibody. See Amendment #1 to the RFP.

Question 5 In the Statement of Work B. and Sample Task Order #1-3; please provide the specific requirements for shelf life, dosage, form and storage requirements and conditions.

Assume for Tasks #1-3 that the final products will be lyophilized.

Question 6 Is there a deadline for submitting questions on this Request for Proposal?

There is no written deadline for submitting questions on this Request for Proposal; however, NIAID would like to encourage all prospective offerors to get questions in early. The Government does not anticipate that it will extend the due date for Receipt of Proposals even if questions are received close to the due date.

The following sections of this RFP are amended as set forth below:

- **Section J, Paragraph C, the first paragraph is revised to read as follows:**

PAGE LIMITS - THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 250 PAGES INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc. Any portions of your proposal not available electronically are also considered to be included in the total page limitation. Pages in excess of this limitation will be removed from the proposal and will not be read or evaluated. The Government will exempt relevant publications from the 250 page limit and relevant publications are the only items allowed to be included in an Appendix that are exempt from these page limits.

- **On pages 27, ARTICLE I.3 – Additional Contract Clauses, delete the following:**

HHSAR 352.270-9, Protection of Human Subjects (January 2001)

- **On page 30, Section J – LIST OF ATTACHMENTS, delete the following:**

Inclusion Enrollment Report

-Pages 44-48, INSTRUCTIONS TO OFFERORS, the following sections are deleted from this RFP:

(9) Human Subjects, (10) Instructions to Offerors Regarding Protection of Human Subjects, and (11) Required Education in the Protection of Human Research Participants

-Pages 64 –66, SECTION M – EVALUATION FACTORS FOR AWARD, item 2. - HUMAN SUBJECT EVALUATION is deleted in its entirety from this RFP.

-Page 3, INTRODUCTION/BACKGROUND, paragraph 3, is revised as follows:

Delete the following sentence, "The Executive Committee will determine the project work assignments of subcontractors to accomplish the task." This sentence is amended to read, "The Executive Committee will be responsible for making recommendations to the PI for the coordination and implementation of contract activities; however, final responsibility for all deliverables rests with the PI."

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DMID-03-32 remain unchanged and in full force and effect.

The hour and date specified for receipt of offers is **NOT** extended.

Offerors must acknowledge receipt of this Amendment #2, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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